



Merlin

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2. Summary of Safety and Effectiveness

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Device identification: Trade Name: UpScan 120
Model Number: ME-955
Common Name: Video Scan Converter (or Digital Scan Converter)
Classification Name: (A component of) stationary x-ray system, per 21 CFR 892.1689 (or equivalent)

Device(s) to which substantial equivalence is claimed: K953398 UniScan Merlin Engineering Works
K954211 CrisPics Merlin Engineering Works

Description of the device: UpScan 120 is a digital image processing system that can convert from low-line rate video standard of 525/30 (or 625/25) or high-line rate video standard of 1023-1049/30 (or 1249/25), to very-high-line rate video standard of 1023-1049/60 (or 1249/50), often referred to as "flicker free" or "fast" video. Additionally, UpScan 120 can provide a (pre-)fixed amount of vertical edge enhancement to the output video signal, and can also invert the video image (black \leftrightarrow white). Housed in a 1 3/4" EIA rack mount chassis, UpScan 120 operates from 100V to 240V AC power.

Intended use of the device: The intended use for UpScan 120 is conversion of X-ray (stationary, C-arm, angiography, etc.), nuclear medicine, magnetic resonance, and ultrasound images either directly from their source, or from an intermediate storage device (like a video tape or video disk), for use on high resolution display monitors or other apparatus requiring a very-high-line rate video signal (e.g., 1023-1049 lines @ 60 frames/second, or 1249 lines @ 50 frames/second). The use of UpScan 120 is indicated whenever the source and destination of a video signal are incompatible due to different line and/or frame rates, and a very-high-line rate video signal is required. UpScan 120 is intended for use in patient care areas, but is not intended to have any patient contact.

Technological characteristics of the device:

UpScan 120 consists of an enclosed sheet metal chassis housing one main printed wiring assembly, one secondary printed wiring assembly, and the power supply (100-240 VAC input and ± 15 VDC, ± 5 VDC outputs).

UpScan 120 uses standard SSI/MSI/LSI semiconductor technology.

UpScan 120 utilizes nine basic electronic circuits on the primary printed wiring assembly. They are: input analog video conditioning circuit, analog-to-digital conversion circuit, memory circuits, digital video line interpolator circuits, digital processing circuits, various control circuits, digital-to-analog conversion circuit, two clock circuits, and output analog video conditioning circuit.

All of the processing is done in the digital domain. The analog-to-digital converter changes the analog video to an 8-bit digital bus. That digital bus is sent to the memories for processing. Memory control circuits manage the locations and the timing of how the video is being stored in the memories. The line interpolator circuits interpolate the output digital bus from the memories, and the digital processing circuits add desired vertical edge enhancement and/or video inversion before sending the resultant signal to the 8-bit digital-to-analog circuit.

The write clock generator provides clock timing for analog-to-digital conversion, the memories and the memory control circuits. The read clock generator provides read clock timing for the memories, the line interpolator and the digital-to-analog circuits.

Summary of how the technological characteristics compare to predicate device(s):

UpScan 120 and one of the predicate devices (Merlin UniScan) are real-time video processing systems which are designed to convert monochrome video images from one video format to another. The only differences are a higher clock frequency and the ability to output video at twice the standard frame rate. UpScan 120 and the other predicate device (Merlin CrisPics) are real-time video processing systems designed to provide edge enhancement and/or video inversion for monochrome video signals.

UpScan 120 and all of the predicate devices utilize similar technology to perform their functions. These systems all convert the incoming analog video signal to digital form using 8-bit analog-to-digital converters, process the signals in the digital domain, and convert back to analog video using 8-bit digital-to-analog converters for the output.

Summary of (non-clinical) performance tests and how their results support a determination of substantial equivalence:

UpScan 120 was tested to ensure that it meets the appropriate requirements of RS-170 and RS-343A. The data demonstrates that UpScan 120 meets these requirements, as is the case for the predicate devices.

In addition, UpScan 120 was tested in accordance with SMPTE RP-133. The system correctly compensates for aspect ratio changes, and it permits low-contrast imaging resolution at the 1% level.

Conclusions drawn from the performance tests:

UpScan 120 is electrically compatible with industry standard monochrome video signals. The image quality is preserved (within the limits of standard video technology).